JS 44 (Rev. 09/11)

CIVIL COVER SHEET

The JS 44 civil coversheet and the information contained herein neither replace nor supplement the filing and service of pleadngs or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States inSeptember 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Medical Mutual of Ohio

(b) County of Residence of First Listed Plaintiff Out of State Resident
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Nicholas E. Chimicles, Joseph G. Sauder, Christina Donato Saler, Benjamin F. Johns, Chimicles & Tikellis LLP, 361 W. Lancaster Ave., PA 19041 (610) 642-8500

DEFENDANTS
SmithKline Beecham Corporation, d/b/a/ GlaxoSmithKline, plc

County of Residence of First Listed Defendant Philadelphia
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☒ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

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- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
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- ☐ 196 Franchise

REAL PROPERTY
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- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
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- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Med. Malpractice

PERSONAL INJURY
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- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
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- ☐ 371 Truth in Lending
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- ☐ 540 Mandamus & Other
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FORFEITURE/PENALTY
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- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
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- ☐ 830 Patent
- ☐ 840 Trademark

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- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

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- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
Monopolization under State Statutes; Unfair and Deceptive Trade Practices Under State Statutes
Brief description of cause:
Blocking market entry of less expensive generic versions of Flonase

VII. REQUESTED IN COMPLAINT:
☑ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23
DEMAND $
CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*: JUDGE J. Brody DOCKET NUMBER 08-3301

DATE 07/24/2012

SIGNATURE OF ATTORNEY OF RECORD Christina Donato Saler

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

CHIMICLES & TIKELLIS LLP
Nicholas E. Chimicles, Pa. Id. No. 17928
Joseph G. Sauder, Pa, Id. No. 82467
Christina Donato Saler, Pa. Id. No. 92017
Benjamin F. Johns, Pa. Id. No. 201373
One Haverford Centre
361 West Lancaster Avenue
Haverford, PA 19041
Phone (610) 642-8500
Fax (610) 649-3633

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

Medical Mutual of Ohio, on behalf of itself and all others similarly situated, Plaintiff, v. SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE plc, Defendant.	**CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

CLASS ACTION COMPLAINT AND JURY DEMAND

Plaintiff, Medical Mutual of Ohio ("Medical Mutual" or "Plaintiff") brings this nationwide class action on behalf of itself and a proposed class of Third Party Payors of the prescription drug Flonase and its generic equivalent, fluticasone propionate. For this Class Action Complaint ("Complaint") against Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline plc ("Defendant" "the company" or "GSK") Plaintiff alleges as follows based on personal knowledge, the investigation of its counsel, the review of pleadings and court orders in patent infringement and other litigation concerning the conduct at issue in this action, and information and belief:

I. NATURE OF THE ACTION

1. Plaintiff brings this nationwide class action against Defendant on behalf of itself and a proposed class of Third Party Payors of the prescription drug Flonase and its generic equivalent (fluticasone propionate) who did not purchase the drug for resale. This lawsuit centers on GSK's filings of groundless citizen petitions with the Food and Drug Administration (the "FDA" or "the agency") for the exclusive purpose of obstructing the entry of generic Flonase into the market. GSK's filings constituted an abuse of the citizen petition process established by Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA").

2. The four petitions that GSK filed with the FDA illegally delayed the FDA's impending approval of generic Flonase, a drug that treats the nasal symptoms of allergies. The petitions lacked any legitimate basis. They were submitted as part of GSK's corporate strategy to maximize its profits by using any means available—whether illegal or not—to extend the duration of its drug monopolies. GSK's employees and agents knew that the FDA would reject the series of petitions, but also knew that the petitions would trigger the FDA's review process, which would provide GSK with an additional period of time during which it would be able to sell Flonase unhindered by any competition. In rejecting the petitions, the FDA disparaged them as transparent attempts by GSK to prolong its grip on the Flonase market, stating: "GSK is not permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved."

3. GSK's objectively baseless petitions served to block the introduction of cheaper generic versions of Flonase into the U.S. market at an earlier date, injuring Plaintiff and members of the class. GSK's anticompetitive scheme to keep generic fluticasone propionate off the market allowed GSK to wield monopoly power in the U.S. Flonase market for at least 20 months longer than it otherwise would have. During this time, GSK sold over $1 billion of Flonase at supra-competitive prices. GSK

overcharged Plaintiff and members of the proposed class by millions of dollars, denying them the benefits of unrestricted competition and access to cheaper generic versions of Flonase.

4. As a result of GSK's misconduct, Plaintiff seeks treble damages, where appropriate.

II. PARTIES

A. Plaintiff

5. Medical Mutual of Ohio is a non-profit corporation organized and existing under the law of the State of Ohio which maintains its headquarters at 2060 East Ninth Street, Cleveland, Ohio 44115. Medical Mutual of Ohio provides fully insured benefits to its members and, through its wholly owned subsidiary, Medical Mutual Services, LLC (collectively "MMO"), provides administrative services, including recovery services for its clients. MMO was an Indirect Purchaser of Flonase and its generic equivalents during the Relevant Period and was injured by the Defendant's unlawful conduct, as alleged herein. MMO sustained injury when it purchased, paid for and or provided reimbursement for Flonase and its AB-rated generic equivalents during the relevant period in the states of Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Maine, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Oregon, Tennessee, Texas, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin and the District of Columbia and, therefore, paid more in these states than it would have absent the Defendant's unlawful conduct.

B. Defendant

6. Defendant SmithKline Beecham Corporation is a Pennsylvania Corporation with its principal office located at One Franklin Plaza, Philadelphia, Pennsylvania. SmithKline Beecham also conducts business in the name of GlaxoSmithKline Inc. and is a subsidiary of GlaxoSmithKline plc.

Defendant maintains major research, development, and production facilities in North Carolina, including Research Triangle Park, North Carolina and Greenville, North Carolina.

III. JURISDICTION AND VENUE

7. This Court has jurisdiction over these actions pursuant to the Class Action Fairness Act of 2005 ("CAFA"), 28 U.S.C. §1711, *et seq.,* which vests federal district courts with original jurisdiction over any multi-state class action where the aggregate amount in controversy exceeds $5,000,000 and the citizenship of any member of the class of plaintiff is different from any defendant. The diversity and amount in controversy requirements of CAFA are satisfied in this case.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §1391(a) and (c) because a substantial part of the events giving rise to the claims asserted herein occurred in this judicial district and because GSK transacts business in this judicial district.

9. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. According to statistics released by the federal government, over $216 billion of prescription drugs were dispensed in the United States in 2006. The sale of prescription drugs in the United States grew to approximately $286.5 billion in 2007. With approximately $712 billion in global pharmaceutical sales in 2007, third-party payors in the United States account for more than one-third of the world's prescription drug revenues.

IV. LEGAL BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs

10. Under the FDCA, codified at 21 U.S.C. §§301-392, manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. §355(a), (b).

11. In 1984, Congress modified the FDCA by enacting the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). The modification, more typically known as the Hatch-Waxman Amendments, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. Instead, the FDA provides an expedited review process by which generic manufacturers file an abbreviated application (an "ANDA") which relies in substantial part on the scientific finding of safety and effectiveness included by the brand named manufacturer in the NDA for the same drug. 21 U.S.C. §355(j).

12. Two primary goals motivated the enactment of the Hatch-Waxman Amendments. First, where a generic product could be developed that did not infringe any existing legitimate patent, Congress sought to expedite the entry of generic competitors and thereby reduce healthcare expenses nationwide. Second, Congress wanted to protect the incentive of pharmaceutical companies to create new and innovative products. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches, and ushering in an era of historic high profit margins for brand name pharmaceutical companies.

13. Under the terms of the FDCA and the Hatch-Waxman Amendments, a prospective generic manufacturer must demonstrate to the FDA that the generic drug it proposes to market is bioequivalent to the brand named drug. 21 U.S.C. §355(j)(2)(A)(iv). The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients in the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another.

14. Bioequivalency demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. §355(j)(8)(B). For drugs that are not intended to be absorbed into the bloodstream, including Flonase, the Hatch-Waxman Amendments provide that the FDA "may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect." 21 U.S.C. §355(j)(8)(C); 21 C.F.R. §320.24 (b)(6).

15. In reviewing what "alternative, scientifically valid methods" it might consider in determining bioequivalence of drugs, the FDA may – but is not required to – issue a guidance document articulating the agency's current thinking on the issue. No regulations require the FDA to issue such a guidance document, however, and guidance documents, where they exist, do not bind either the FDA or the public as they do not establish legally enforceable rights or responsibilities. Rather, the guidance documents are just that – they embody the FDA's current thinking on a subject and provide guidance to the public. The FDA's obligation to make a determination as to whether an individual ANDA meets statutory requirements and thus should be approved depends in no part on whether or not a guidance document relevant to that ANDA exists.

16. As a counter-balance to this abbreviated approval procedure for bioequivalent generic drugs, the Hatch-Waxman Amendments streamlined the process for brand name manufacturers to enforce legitimate patents they may hold against infringement by generic manufacturers. Beyond traditional patent rights, the Hatch-Waxman Amendments also provide brand name manufacturers with several means to obtain legitimate protection from generic competition for set, and specifically limited, periods of time. For example, each approved NDA provides the owner of that drug with three years of exclusivity during which time no generic manufacturer can even file an ANDA. 21 U.S.C.

§355(j)(5)(F)(iii). Pioneer drugs or truly new or innovative drugs that make use of a never-before-approved chemical entity or moiety receive even more time: a "New Chemical Entity" ("NCE") exclusivity period of five years. 21 U.S.C. §355(j)(5)(F)(ii).

B. Generic Drugs Offer Significant Savings and Thus Take Significant Sales From Brand Name Drugs

17. Drugs proven to meet bioequivalence requirements through *in vivo* (clinical) and/or *in vitro* (laboratory) testing receive an "AB" rating from the FDA, indicating they are therapeutically equivalent to other drugs with the same rating in the same category. For example, Roxane Laboratories, Inc.'s ("Roxane") fluticasone propionate is an AB-rated generic version of GSK's Flonase, indicating the drugs are therapeutically equivalent and bioequivalent to one another.

18. Typically, manufacturers of AB-rated generic versions of brand name drugs price their drugs significantly below the brand name counterparts. Because of the price differential and certain institutional features of the pharmaceutical market which seek to capitalize on this price differential, AB-rated generic versions are rapidly and substantially substituted for their brand name counterparts.

19. Under the statutory regime enacted by Congress (*i.e.*, the Hatch-Waxman Amendments) and as found in most state legislatures (*i.e.*, Drug Product Selection, or "DPS laws"), pharmacists may – and, in most states, must – substitute an AB-rated generic version of a drug for the brand name drug without seeking or obtaining permission from the prescribing doctor.[1] Congress and state legislatures actively encourage generic substitution of brand name drugs because of the enormous cost savings to purchasers generated.[2]

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[1] The exception to this general rule appears when the prescribing physician indicates "dispense as written" or "DAW" on the prescription. In such instances, pharmacists may not substitute a generic version of the drug.

[2] Federal and state legislatures also recognize that the economics of the pharmaceutical industry prevent generic manufacturers from engaging in the heavy promotion or "detailing" typically done by brand name manufacturers.

20. Once a physician writes a prescription for a brand name drug such as Flonase, the prescription defines and limits the options to the named drug and its AB-rated generic equivalent(s). Only drugs which carry the FDA's AB generic rating in that category may be substituted by pharmacists for a physician's prescription for a brand name drug.

21. If an AB-rated generic formulation of a name-brand drug exists and the physician has not specifically indicated on the prescription "DAW," for "dispense as written" (or similar indications), then: (a) for patients covered by most prescription drug benefit plans, the pharmacist will substitute the generic drug; and (b) for patients whose purchases are not covered by prescription drug benefit plans, the pharmacist will offer the patient the choice of purchasing the AB-rated generic at a lower price. One private insurance company explains in its membership materials that:

> Generic drugs meet strict Food and Drug Administration (FDA) requirements. They are recognized by physicians, the FDA and pharmacists to be as safe and effective as brand-name drugs, but are *much less expensive*. . . . Originally developed as brand-name drugs, the drugs are no longer patent-protected and may be manufactured by other companies without the product name, so the costs of development and advertising aren't passed on to the consumer. The difference in cost between generic and name-brand drugs can be significant. Brand-name drugs typically cost four to five times more than their generic equivalent without *any* difference in medical effectiveness.

(Emphasis in original.)

22. Generic drugs are invariably priced below the branded drugs to which they are bioequivalent. A report prepared by the Government Accounting Office in August 2000 observed: "Because generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs." A Federal Trade Commission study in July 2002 concluded that "[b]ecause generic drugs are typically far less expensive than their corresponding brand-name versions, competition from generic drugs can deliver large savings to consumers."

23. A branded drug loses a significant portion of its market share to generic competitors less than one year after the introduction of generic competition, even if the name-brand manufacturer reduces prices to meet competition. In testimony before Congress, a representative from the Pharmaceutical Research and Manufacturers of America (a name-brand pharmaceutical manufacturers' trade association), confirmed that "in most cases, sales of pioneer medicines drop as much as 75 percent within weeks after a generic copy enters the market."

24. Generic competition enables the purchase of generic versions of brand name drugs at substantially lower prices. Such competition also results in reduced prices for, and thus savings on purchases of, the brand name drug (as the brand manufacturer lowers prices in an attempt to maintain market share). Prior to entry of an AB-rated generic and competition, however, brand name manufacturers can charge supra-competitive prices without losing all, or a substantial portion, of its brand name sales. Consequently, brand name drug manufacturers have strong incentives to delay the introduction of AB-rated generic competition into the market.

C. Citizen Petitions to the FDA

25. Recognizing the central role that healthcare and pharmaceutical drugs play in the United States, Congress enacted federal regulations governing the FDA that allow individuals to express genuine concerns about safety, scientific, or legal issues regarding a product anytime before, or after, its market entry. Under these regulations, any person or entity, including a pharmaceutical company, may file a citizen petition with the FDA requesting that the FDA take, or refrain from taking, any administrative action. 21 C.F.R. §10.30.

26. Within 180 days of receipt, the FDA Commissioner must respond to each citizen petition and may approve the request in part or in full, deny it, or provide a tentative response with an estimate on a time for a full response. 21 CFR §10.30(e)(2).

27. Reviewing and responding to these petitions often requires the use of substantial time and resources because the FDA must, in addition to its already-existing workload: (a) research the subject matter of the citizen petition; (b) examine scientific, medical, legal, and sometimes economic issues; (c) consider public responses to the citizen petition; and (d) coordinate internal agency review and clearance of the petition response. These activities can and do strain the FDA's limited resources.

D. Named Brand Manufacturers Use Citizen Petitions to Forestall Generic Competition

28. Citizen petitions have become a prime vehicle for big pharmaceutical companies to block generic entry and prolong their grip on the market for a given drug. In recent years, a number of brand name pharmaceutical manufacturers abused the citizen petition process, using it as a tactic to extend their monopolies on name brand drugs.[3] Citizen petitions by rival companies rarely raise legitimate concerns about the safety or efficacy of generic products, and instead only seek to preserve monopolies after the end of a statutorily-granted patent or FDA exclusivity period. Companies frequently file these citizen petitions on the eve of FDA approval of an ANDA for competing AB-rated generic drugs, even though the petitioner could have made the same arguments months, or even years, before. This results in delay of final approval of a pending ANDA for several months or more while the FDA evaluates the merits of the citizen petition.

29. The resulting delay of generic competition can be lucrative for an incumbent brand name manufacturer facing impending competition from an AB-rated generic. The cost of filing an improper, sham citizen petition pales in comparison to the value of securing an additional period of monopoly profits.

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[3] See Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission, at *http://www.ftc.gov/be/v000005.pdf*, at p. 1, *et seq*.

30. Indeed, the Hatch-Waxman regime opened the door to anti-competitive tactics designed to delay generic competition and extend the name-brand company's monopoly. In testimony given before Congress, Bruce Downey, the Chairman and Chief Executive Officer of Barr, testified:

> Unfortunately, the delicate balance struck by Congress in 1984 [in Hatch-Waxman] has gradually grown lopsided in favor of the brand name pharmaceutical industry, hostile to the generic industry, and as a direct result, become a threat to the expansion of consumer savings. The reason is simple: the brand industry discovered years ago that competition is good for consumers but bad for their bottom line.
>
> When Hatch-Waxman was implemented, the assumption was that the brand products would lose about 30% of their market, but would recover this loss through price increases. However, the introduction of a generic product often results in such a significant market share loss—as much as 80-90%—that the brand company is not able to recover its loss. After starting their own generic businesses, and implementing other strategies, it became clear to brand companies that the only way to succeed was to delay competition for as long as possible.
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> ***
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> To preserve their monopolies, brand companies have turned to such tactics as patent evergreening, ***citizen petitions***, application of the automatic stay in patent litigation, application for pediatric exclusivity, and other techniques that delay generic approval or prevent timely introduction of generic competitors. (Emphasis added.)

31. In recent years, only about 7% of citizen petitions regarding the approvability of generic products led to any change in the FDA's policy on the basis of data or information submitted in the petition. Yet prior to 2007, the FDA maintained a practice, well known in the pharmaceutical industry, of considering and responding to relevant citizen petitions prior to approval of an ANDA to assure itself that the petitions did not present any new issues or issues of concern.

32. Many informed observers have identified the filing of FDA citizen petitions with anticompetitive intent and effect as a serious problem. For example, Federal Trade Commissioner Jon Leibowitz stated: "The citizen petition process is ripe for abuse. It's no secret that these are filed at the 11th hour, and most are denied. . . . The cost to file is low, but the benefit to brands is high." Available

at: http://www.ftc.gov/speeches/leibowitz/060929GPHA

pubvers.pdf.

33. Likewise, David Balto, a former assistant director in the Federal Trade Commission's Bureau of Competition, observed that a company can "inflict substantial harm on a competitor" "for a relatively small amount of money" by filing a citizen petition before the FDA approves the competitor's ADNA. Pamela A. MacLean, "Business Battle Over Generic Drugs Heats Up With Stalling Tactics," NATIONAL LAW JOURNAL, July 6, 2007.

1. Congress Responded to the Drug Companies' Abuses in 2007 by Empowering the FDA to Summarily Dismiss Citizen Petitions

34. The abuse of the citizen petition process in part helped lead Congress to enact the FDA Amendments Act of 2007, 21 U.S.C. §355(q) (the "2007 Amendments"). In pertinent part, the 2007 Amendments provide that the FDA shall not delay approval of a pending ANDA because of a citizen petition unless the FDA determines that a delay is necessary to protect the public health. The 2007 Amendments also authorize the FDA to summarily deny any citizen petition whose primary purpose, as determined by the FDA, is to delay competition. Signed into law on September 27, 2007, these revisions were not yet in effect at the time the FDA was considering the petitions at issue in this case.

35. The legislative history of the 2007 Amendments, as documented in the Congressional Record, indicates that members of Congress were aware of, and strongly condemned, the same abuse of citizen petitions that lies at the heart of this lawsuit.

36. Senator Kennedy, for example, stated that "citizen petitions . . . are too often used not for their intended purpose of bringing important public health concerns to the attention of the FDA, but rather to delay the approval of generic drugs. . . . Even if the petitions are found to be meritless, they will have accomplished their mission—delaying access for consumers to safe and lower cost medicines. . . . Let us be clear. The citizen petition provision [of the 2007 Amendments] is designed to

address attempts to derail generic drug approvals. Those attempts, when successful, hurt consumers and the public health." 1553 Cong. Rec. S. 1183; 1553 Cong. Rec. S. 11937.

37. Senator Kohl stated that, "[i]n recent years, FDA officials have expressed serious concerns about the abuse of the citizen petition process. In 2005, FDA Chief Counsel Sheldon Bradshaw noted that '[t]he citizen petition process is in some cases being abused. Sometimes, stakeholders try to use this mechanism to unnecessarily delay approval of a competitor's products.' He added that he found it 'particularly troublesome' that he had 'seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application, but rather to delay approval by compelling the agency to take the time to consider the arguments raised in the petition, regardless of their merits, and regardless of whether the petitioner could have made those very arguments months and months before.'" 153 Cong. Rec. S. 5444.

38. Senator Thune stated: "A citizen petition is intended to be just that – it is a petition that is filed by an individual or a group in order to raise potential concerns. If you look at what has happened with that, that process has been abused. . . . What has happened in this process is it has become hijacked and is being used for purposes for which it was not intended." 153 Cong. Rec. S. 5634.

39. Senator Brown noted that, "[u]nfortunately, some brand-name pharmaceutical companies have regularly exploited the citizen petition process, filing frivolous petitions solely for the purpose of delaying the approval of generic drugs. They have been quite successful at it. Since 2003, brand drug companies have filed dozens and dozens of citizen petitions trying to stop or delay FDA approval of competing generic products. Ninety-five percent – roughly 19 in 20 – of these petitions have been denied outright. What about the other 5 percent? FDA either hasn't acted on them or has

approved them in whole or in part because they had no other choice – the brand companies had simply reiterated a factual issue that had already been addressed by FDA. In other words, even the approved petitions, the approved 5 percent, were frivolous. While drugmakers waste FDA's time and taxpayers' money, American patients are forced to continue paying top dollar – the name-brand price – for the medicines they need." 153 Cong. Rec. S. 5444.

40. Senator Stabenow stated: "Simply put, citizen petitions have become pharma petitions to block consumers from having access to affordable medicines, unfortunately. The cost to employers, consumers, health insurance plans, and government health plans, as a result of delayed entry of generics, amounts to hundreds of millions of dollars – and in some cases billions of dollars. The brandname companies often file these petitions right on the eve of the generic drug being approved, making it very clear that delay is the goal." *Id.*

V. FACTUAL BACKGROUND

A. Flonase

41. GSK manufactures, markets, and sells Flonase, a brand-name-prescription drug. Flonase, the generic name for which is fluticasone propionate, is a corticosteroid nasal spray used for treatment of nasal symptoms of seasonal and year-round allergies, as well as nonallergic rhinitis in adults and pediatric patients four years of age and older.

42. The active ingredient in Flonase is a corticosteroid: fluticasone propionate. Flonase consists of an aqueous suspension of micro fine fluticasone propionate intended for topical administration to the nasal mucosa through a metered atomized spray pump. The device is made up of a container, a pump and an actuator.

43. Flonase belongs to a class of medications called intranasal corticosteroids that reduce inflammatory reactions that may lead to nasal symptoms such as congestion, sneezing, and itchy, runny nose.

44. Flonase, as acknowledged by GSK in its promotional materials related to the drug, offers unique attributes among allergy medications in that it is non-habit forming and does not cause drowsiness. It is the only drug approved to treat the nasal symptoms of indoor and outdoor allergies as well as year-round nonallergic nasal symptoms.

B. Approval and Sale of Flonase

45. The FDA approved the NDA for GSK's Flonase Nasal Spray (in 50 mcg) for sale in the United States on October 19, 1994. The agency subsequently approved several supplements to the Flonase NDA in order to add new labeling information, including new indications for use.

46. GSK held a single patent on Flonase which expired on November 14, 2003. Having fulfilled certain requirements regarding pediatric studies, GSK received a six-month extension of market exclusivity from the FDA.[4] Thus GSK's exclusive right to market Flonase in the United States expired on May 14, 2004 and with final approval by the FDA, a generic manufacturer could have begun marketing a generic form of Flonase on or after that date.

47. Prior to entry of generic forms of fluticasone propionate, Flonase held 100% of the relevant market. GSK marketed and sold Flonase in the U.S., yielding annual sales of approximately $930 million in 2004 and over a billion dollars in 2005. The pharmaceutical industry publication *Drug Topics' Top 200 Brand Name Drugs by Dollars* ranked Flonase at number 37 in 2004 and number 33 in 2005.

C. FDA'S Preparation for Approval of Generic Competition for Flonase

48. In June 1999, the FDA initiated a guidance development process to establish a standard approach for measuring the bioequivalence of nasal suspension and nasal spray products. After

[4] Section 505A of the FDCA provides for a six-month extension beyond the expiration of the relevant patent during which time an ANDA may not be approved if the FDA determines it desires information about the drug in pediatric populations, and if certain conditions regarding studies of the drug in that populations are met.

receiving comments from the public and the pharmaceutical industry, the FDA in 2003 issued the guidance document in draft form. *See* FDA Draft Guidance, *Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action*, April 2003 ("2003 Draft Guidance").

49. FDA guidance documents simply embody the FDA's current thinking on a subject and provide guidance to the public; they are only recommendations meant to solicit public comment and input. Guidance documents do not bind the FDA and they do not restrict the FDA's ability to consider methodologies or processes other than those articulated in the guidance document. The FDA's obligation to make a determination as to whether an individual ANDA meets statutory requirements and thus should be approved depends in no part on whether or not a guidance document relevant to that ANDA exists. *See generally* 21 C.F.R. §10.115(d).

50. The FDA approves a multitude of generic drugs without benefit of any relevant guidance document, in draft or final form. If the FDA had to finalize guidance documents prior to taking any relevant administrative action, generic drug approvals stemming from ANDAs would face significant delays. The FDA stated: "[i]f the FDA were required to answer questions from potential generic drug applicants by issuing guidance documents, it would be impossible for the Agency to fulfill its responsibility under the Act to approve every generic drug that meets the statutory standards." *See* FDA's consolidated response to submissions regarding ANDAs for fluticasone propionate, attached as Exhibit 1, at p. 22 ("FDA's consolidated response").

51. Federal statutes require that in evaluating generic drugs for approval, the FDA must use its own scientific judgment when analyzing bioequivalence data to determine whether there is a "significant difference" in the rate and extent of absorption of the drug between the brand name and proposed generic.

52. The FDA articulated scientifically valid methodologies for making this determination in the 2003 Draft Guidance. The FDA approach to establish bioequivalence for locally acting nasal suspension spray relies on "(1) qualitative and quantitative sameness of formulation of test and reference products, (2) comparability in container and closure systems, and (3) *in vitro* and *in vivo* methods that demonstrate equivalent product performance." *Id.* at p. 5 (citing 2003 Draft Guidance).

53. Product quality standards are also an important consideration for the FDA both for brand name and generic drugs. In 1997, the FDA began recommending that manufacturers seeking approval of nasal sprays include specifications for droplet size distribution ("DSD") and spray pattern ("SP") to help evaluate product quality.

54. Because a nasal spray pump delivers a drug locally (to the nasal mucosa) rather than through the bloodstream, the FDA and manufacturers must consider the amount and method of delivery to the affected area in evaluating the amount of active ingredient provided by each application of the drug. In addition, manufacturers and the FDA must be able to show that, within a certain acceptable variation, each actuation of the nasal pump delivers the same amount of active ingredient to ensure consistent performance over the lifetime of the device. DSD and SP demonstrate, in part, these important considerations.

55. For generic drugs, "the specifications ensure that each production batch of generic…nasal spray meets the standards for drug quality (*i.e.*, delivers clinical performance per label claims), based on batches that have been demonstrated to be bioequivalent with [the brand name nasal spray]." *Id.* at 21. The exact specifications used may differ from manufacturer to manufacturer based on the equipment and testing conditions used. Such differences are perfectly acceptable as long as the products all meet the same standard for product quality.

56. The FDA approved Flonase before it began recommending nasal spray applicants include DSD and SP specifications, but soon requested GSK submit such information. As part of a 1999 supplement to its NDA, GSK submitted specifications for DSD and DS to the FDA. In response, the FDA requested that GSK tighten the acceptable limits and reduce variation in SP and DSD and that GSK test the SP and DSD of each batch of Flonase. In October 2004, the FDA approved final DSD and SP specifications for Flonase based on GSK's reduction in variation in SP and DSD. GSK, with the FDA's knowledge and blessing, continued to sell Flonase as a safe and effective drug during these years.

D. GSK's Unlawful Scheme to Delay Generic Competition for Flonase

57. As a sophisticated and long-standing pharmaceutical manufacturer, GSK knew that as its patent exclusivity for Flonase approached, generic manufacturers would seek approval from the FDA to market a generic version of the drug. GSK also knew that such ANDAs would be filed with the FDA in time for the FDA to carefully consider them and issue approval prior to or concomitant with the expiration of GSK' s market exclusivity.

58. On October 3, 2002, more than a year before GSK's patent expired and more than a year and a half before GSK's statutorily-regulated market exclusivity expired, Roxane filed an ANDA with the FDA seeking approval to market an AB-rated generic version of Flonase upon the expiration of GSK' s period of market exclusivity.

59. On May 19, 2004 – just days after the expiration of GSK's Flonase exclusivity and on the eve of what would have been the FDA's approval of Roxane's ANDA – GSK filed an objectively baseless citizen petition with the FDA for the express purpose, and with the express intent, of delaying the FDA's final approval of any generic manufacturer's ANDA thus delaying generic competition in the United States market for fluticasone propionate. Over the next year, GSK filed additional objectively baseless submissions with the FDA, including a Supplement to the Citizen Petition on November 23,

2004, a Petition for Stay of Action on March 25, 2005, and a Second Supplement to the Citizen Petition on June 16, 2005.

1. GSK's Citizen Petition (First Petition) Lacked Any Legitimate Grounds

60. On May 19, 2004, five days after its exclusivity period for Flonase expired but more than a year and a half after Roxane filed its ANDA for a generic version of the drug, GSK filed an objectively baseless citizen petition with the FDA. *See* GSK Citizen Petition, dated May 19, 2004, attached as Exhibit 2 ("GSK's First Petition").

61. In that Petition, GSK acknowledged that the FDA "may be nearing an approval decision on an ANDA" for generic fluticasone propionate. *Id.* at p. 2.

62. GSK's First Petition did not address the adequacy of Roxane's ANDA, present any evidence that Roxane's fluticasone propionate failed to demonstrate bioequivalence to Flonase, or raise any concerns about public health – the issues for which citizens petitions were primarily implemented. Instead, GSK's First Petition urged the FDA to refrain from approving any AB-rated ANDA for fluticasone propionate until after the FDA completed the process of issuing a final guidance document setting forth a scientifically valid methodology for determining bioequivalence for nasal spray products.

63. GSK's citizen petition urged the FDA not to act on any ANDAs for fluticasone propionate until completing the guidance development process, which would presumably include another lengthy period of public comment and the issuance of a final form of the 2003 Draft Guidance. GSK's First Petition argued that prior to approval of any ANDA, the FDA must first develop statistical criteria for *in vitro* and *in vivo* comparative tests, direct that *in vivo* clinical studies be conducted in the "most difficult to treat" indication, and direct that any ANDA applicant conduct certain pharmacokinetic studies. GSK's First Petition at p. 2-3.

64. GSK's First Petition was a sham. GSK could not reasonably have expected to prevail on the substance of the Petition. Though it purported to be caught unaware that the FDA would even

consider approving an ANDA before finalizing the 2003 Draft Guidance, GSK, a sophisticated and long-standing player in the pharmaceutical industry, knew that generic manufacturers would file one or more ANDAs seeking approval to market generic Flonase as soon as GSK's exclusivity for Flonase expired. GSK also knew that the FDA faced no law or regulation requiring it, nor was it FDA's practice, to finalize relevant guidance documents prior to evaluating a pending ANDA or taking other administrative action.

65. The FDA rejected GSK's petition, stating:

> Neither the Act nor the FDA regulations require the FDA to issue final guidance prior to approving an ANDA.... GSK has cited no authority to support its position that the Agency must complete a guidance document prior to approving an ANDA for a fluticasone propionate nasal spray product.... Whether or not FDA issues final guidance does not speak to the scientific validity of FDA's bioequivalence methodology, scientific evaluation, and approval of generic fluticasone propionate nasal spray products... Over the past eight or more years, based on industry and public input, FDA has developed a scientifically valid methodology capable of detecting a significant difference between test and reference fluticasone propionate nasal spray products.

Exhibit 1: FDA's consolidated response at p. 21-22.

2. GSK's Supplemental Citizen Petition (Second Petition) Lacked Any Legitimate Grounds

66. On November 23, 2004, six months after the filing of GSK's First Petition, GSK submitted a supplemental citizen petition with respect to fluticasone propionate to the FDA. *See* GSK's Supplement to the Citizen Petition, dated November 23, 2004, attached as Exhibit 3 ("GSK's Supplemental Petition"). Like its previous submission, GSK's Supplemental Petition neither addressed the adequacy of Roxane's ANDA nor presented any evidence that Roxane's fluticasone propionate failed to demonstrate bioequivalence with Flonase. The petition also failed to raise any concerns about public health.

67. Instead, GSK's Supplemental Petition claimed that with respect to product quality, the FDA could not substitute bioequivalence tests as a surrogate for product quality standards. It sought to have the FDA impose on any ANDA filer for fluticasone propionate the same set of standards related to droplet size distribution ("DSD") and spray pattern ("SP") as that imposed by the FDA on GSK's Flonase in October 2004 (supplement S-019 to NDA 20-121).

68. GSK's Supplemental Petition was a sham. GSK could not reasonably have expected to prevail on the substance of the petition.

69. Prior to GSK's 1999 NDA supplement, and during the entire time GSK worked with the FDA to tighten its SP and DSD parameters, GSK continued to sell Flonase as a safe and effective product. Thus, GSK could not reasonably expect that the FDA would refrain from approving an ANDA that lacked SP and DSD standards.

70. Moreover, GSK's Supplemental Petition ignored the fact that the FDA had already recommended that all NDA and ANDA applicants for nasal spray products provide specifications for SP and DSD. *See* 2003 Draft Guidance. *See also* FDA's *Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products – Chemistry, Manufacturing, and Controls Documentation*, July 2002.

71. Although the actual specifications for drug quality between ANDA and NDA products may differ, the FDA requires generic and innovator applicants to meet the same standards for product quality. How that quality is measured differs from drug to drug and from manufacturer to manufacturer due to variations in manufacturing processes, as well as tests developed to measure quality. GSK acknowledged that "A generic drug product need not be manufactured in the same way as the innovator, nor must it necessarily meet identical manufacturing specifications." Exhibit 3: GSK's Supplemental Petition at p. 16.

72. The FDA rejected GSK's petition, stating:

> [e]ach firm develops its own proprietary product quality tests (*e.g.*, to measure DSD and SP) that may use different equipment under different conditions. Because GSK's DSD and SP product quality tests and methodologies are proprietary, it is virtually impossible for a generic manufacturer to perform the exact same tests that GSK used for Flonase approval to compare test and reference products.... ANDA applicants are not expected to have exactly the same product quality specifications as the [NDA product].

Exhibit 1: FDA's consolidated response at p. 20.

73. When it submitted its supplemental petition, GSK knew and understood the requirements with respect to product quality for nasal spray products previously articulated by the FDA. Given the proprietary nature of quality tests and methodologies GSK had employed with respect to Flonase and the fact that the exact standards imposed on Flonase were dependent in part on those proprietary tests, GSK also understood that it was asking the FDA to impose a nearly impossible standard on any ANDA filer.

3. GSK's Petition for Stay of Action (Third Petition) Lacked Any Legitimate Grounds

74. On March 25, 2005, GSK filed a Petition for Stay of Action seeking "a stay of just three business days – beyond the point in time when GSK is first notified of FDA's decision to grant final approval – of the effective date of any approvals FDA may decide to grant of the abbreviated new drug applications...for generic version of Flonase..." Petition for Stay of Action, dated March 25, 2005, Exhibit 4 at p. 1 (emphasis in original) ("GSK's Stay Petition").

75. Federal regulations at 21 C.F.R. §10.35(e) set out the standard for review of a petition for stay of action to the FDA and provide that such a stay may only be granted if the petitioner demonstrates: (1) it will suffer irreparable harm; (2) its case is not frivolous and is being pursued in good faith; (3) it has demonstrated sound public policy grounds supporting the stay; and (4) the delay resulting from the stay is not outweighed by public health or other public interests.

76. Having knowingly failed to provide any legitimate basis in its two prior petitions as to why the FDA should delay approval of any ANDA for generic Flonase and given the FDA's statutory mandate to approve all generic drugs that meet statutory requirements, GSK could not reasonably have expected to prevail in its request for a stay. Instead, GSK submitted the stay application to delay the FDA's approval of Roxane's pending ANDA by requiring the FDA to consider and respond to its application

77. The FDA recognized GSK's Stay Petition as a sham and ruled that "GSK has not articulated sound public policy grounds for supporting a stay." Exhibit 2: GSK's First Petition at p. 23. The FDA noted that "[a]n assumption underlying GSK's argument is that the Agency's approval standards will, upon further examination, be found inadequate. This assumption is too speculative and too unlikely to form the basis of a public policy argument for grant of a stay." *Id.*

78. The FDA further noted: "One of the purposes of the Hatch-Waxman Amendments is to foster the availability of low-cost generic drugs. This important public policy would be frustrated if FDA were to grant the stay GSK requests." *Id* at p. 24.

79. Finally, the FDA explicitly recognized GSK's attempt to monopolize the market and reprimanded Defendant stating: "[t]he policies behind Hatch-Waxman dictate that GSK should not be permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved under section 505(j) of the Act." *Id.*

4. GSK's Second Supplement to the Citizen Petition (Fourth Petition) Lacked Any Legitimate Grounds

80. On June 16, 2005, GSK filed yet another objectively baseless supplement to the citizen petition with the FDA. *See* Second Supplement to Citizen Petition, dated June 16, 2005 attached as Exhibit 5 ("GSK's Second Supplement"). As per course, this petition neither addressed the adequacy of Roxane's ANDA nor presented any evidence that Roxane's fluticasone propionate lacked

bioequivalence to Flonase. GSK's Second Supplement similarly failed to raise any concerns about public health. Rather, it included a declaration from a GSK statistician who had reviewed publicly available *in vitro* study data from FDA bioequivalence review of some approved generic nasal solution products, asserting that the FDA inconsistently applied statistical methods for comparative *in vitro* tests for ANDAs for nasal spray *solution* products, a class to which Flonase (a *suspension*) does not belong.

81. Like its other filings, GSK's Fourth Petition was a sham. GSK could not reasonably have expected to prevail based on the issues raised in this petition. In the 2003 Draft Guidance, the FDA established that it was appropriate to use the Population Bioequivalence ("PBE") method to review and evaluate *in vitro* studies related to nasal spray suspension products. This was the same method that GSK's expert criticized.

82. The FDA rejected GSK's Fourth Petition (the "Second Supplement"), stating that "GSK's arguments...are not relevant to the fluticasone propionate nasal spray suspension products evaluated under the PBE method." Exhibit 1: FDA's consolidated response at p.11.

E. GSK's Repeat Filings Demonstrated Bad Faith

83. On February 22, 2006, the FDA rebuffed GSK's various petitions in a 24-page letter, finding the petitions to be without merit. *See* Exhibit 1: FDA's consolidated response. In this letter, the FDA chastised the company and its motives, writing "GSK is not permitted to shield its market share when the Agency has reasonably determined that competing generic drug products may be approved."

84. On the same date, the FDA issued an approval of Roxane's ANDA for generic Flonase. FDA approval letter to Roxane Laboratories, Inc., dated February 22, 2006, attached as Exhibit 6.

85. GSK then applied for a preliminary injunction seeking to reverse the FDA's denial of its citizen petitions and approval of Roxane's ANDA, but this application was rejected.

86. Roxane began selling generic Flonase in the United States on March 6, 2006 – approximately twenty-two months after GSK's statutorily-granted market exclusivity expired.

87. Thus, GSK's submissions had had their desired effect and had extended the company's monopoly on Flonase in the United States by nearly two years.

88. GSK did not make its series of submissions to the FDA to influence FDA policy or address any legitimate concern about the efficacy or safety of generic fluticasone propionate. Rather, GSK meant solely to forestall generic competition in the United States market for fluticasone propionate during the time it would take the FDA to evaluate and respond to the petitions. GSK, with full knowledge that its exclusivity period for Flonase was approaching expiration and that the FDA was very likely in the process of considering the bioequivalency of one or more generic products, waited until the last possible moment to submit the first of its series of submissions to the FDA, hoping to impose significant delay into the consideration by the FDA of any generic competition. Given the FDA's limited resources and contemporaneous practice of carefully considering all citizen petitions before granting final approval to ANDAs, GSK knew that the filing of a citizen petition would immediately derail the FDA process for approving generic versions of Flonase. GSK's pattern of conduct, under the totality of the circumstances, demonstrates that GSK's motive was to use the petition process itself, as opposed to the outcome of that process, as an anti-competitive weapon and unlawfully extend the company's monopoly for Flonase products in the United States.

F. GSK's Anticompetitive Actions Harmed Plaintiff and Third Party Payor Class Members

89. GSK's unlawful conduct denied Plaintiff and the Third Party Payor Class the benefits of free and unrestrained competition in the market for fluticasone propionate from May 19, 2004, the date of GSK's First Petition, until February 22, 2006, the date the FDA approved generic fluticasone propionate for sale in the United States.

90. Further, the effects of GSK's anticompetitive scheme extended beyond February 22, 2006, because the full extent and benefit of generic penetration does not to occur immediately upon the entry of a generic prescription drug into the market.

91. In his testimony before Congress, Michael Wroblewski of Consumers Union, the non-profit publisher of Consumer Reports, testified: "Flonase, a commonly used prescription allergy medication, went off-patent in May 2004. But GlaxoSmithKline stretched its monopoly window by almost two years with citizen petitions and a legal challenge to the use of generics." Available at: http://judiciary.senate.gov/testimony.cfm?id=2472&wit_id=5985.

92. GSK's unlawful actions denied Plaintiff and members of the Third Party Payor Class the opportunity to purchase lower-priced AB-rated generic versions of Flonase

93. GSK's unlawful actions forced Plaintiff and members of the Third Party Payor Class to pay supra-competitive prices for fluticasone propionate.

94. GSK's acts were part of, and in furtherance of, the illegal monopolization scheme alleged herein, and were authorized, ordered or done by GSK's officers, agents, employees or representatives while actively engaged in the management of GSK's affairs.

VI. INTERSTATE COMMERCE

95. GSK's efforts to monopolize and restrain competition in the market for fluticasone propionate substantially affected interstate and foreign commerce.

96. At all material times, GSK manufactured, promoted, distributed, and sold substantial amounts of Flonase in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

97. At all material times, GSK transmitted funds as well as contracts, invoices and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Flonase.

98. In furtherance of its efforts to monopolize and restrain competition in the market for Flonase and generic forms of Flonase, GSK employed the United States' mails and interstate and international telephone lines, as well as means of interstate and international travel.

VII. RELEVANT MARKET

99. Direct proof exists that GSK had monopoly power over the price of fluticasone propionate in the United States. Such direct evidence includes transactional data showing a significant non-transitory decline in prices of fluticasone propionate immediately upon entry of generic versions of the drug. Such a significant non-transitory decline in prices did not occur until generic entry into the market. This direct evidence of monopoly power obviates the need to define a relevant product market in assessing whether GSK had monopoly power.

100. GSK, as the only seller of fluticasone propionate products in the United States, could and would impose a significant non-transitory price increase without losing sufficient sales to render the price increase unprofitable, as demonstrated by GSK's ability to profitably charge supra-competitive prices during the period in which it was without generic competition. There were no reasonably interchangeable drug products available to prescribing physicians for the indications for which fluticasone propionate is prescribed.

101. To the extent that the law requires Plaintiff to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff allege that the relevant market is all fluticasone propionate products – *i.e.*, Flonase (in all its forms and dosage strengths) and AB-rated bioequivalent fluticasone propionate products.

102. The relevant geographic market is the United States and its territories.

103. Prior to generic versions of Flonase entered the U.S. market in March 2006, GSK held 100% market share in the relevant product and geographic markets. Following market entry by generic manufacturers and much cheaper generic version of Flonase, GSK's market share for fluticasone propionate products declined dramatically in a short period of time.

VIII. MARKET EFFECTS

104. GSK's acts and practices, as herein alleged, had the purpose and effect of unreasonably restraining and injuring competition by protecting Flonase from generic competition in the relevant market.

105. Regulations generally permit – and sometimes even mandate – pharmacists to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. Similarly, many third-party payors of prescription drugs (*e.g.*, managed care plans) encourage or insist on the use of generic drugs whenever possible, thus creating a ready market for generic products.

106. The initial entry of generic products generally leads to a significant erosion of a branded drug's sales within the first year as generic drugs can quickly and efficiently enter the marketplace at substantial discounts.

107. Had generic competitors been able to enter the relevant market and compete with GSK, Plaintiff and the Third Party Payor Class would have paid for lower-priced generics in place of the higher-priced brand name drug. As a result, there would have been far fewer dollars paid for fluticasone propionate products between May 19, 2004 and an as-yet-undetermined date after March 6, 2006, by which point generic versions of Flonase had fully penetrated the U.S. market.

108. GSK recognizes and acknowledged the effects of market entry of generic versions of a drug – both generally and in the specific instance of Flonase competition. Affidavits submitted by GSK in its litigation to block entry of a generic version of Flonase state that the company expected to lose $684 million in gross sales during the first six months of generic competition and a total of $1.25 billion in the first year after generic competition began.

109. Moreover, Senator Thune stated: "Take Flonase, for example. The delay caused by using the citizen petition was 645 days. During that period, the additional sales that were generated were over $1 billion – $1.6 billion." 153 Cong. Rec. S. 5634.

110. By blocking or preventing generic competitors from entering the market, GSK injured Plaintiff and the other members of the Third Party Payor Class in their business or property by causing them to pay more for fluticasone propionate products than they otherwise would have paid. GSK's unlawful conduct deprived Plaintiff and other Third Party Payors for fluticasone propionate products of the benefits of competition that state antitrust laws were intended to preserve.

IX. CLASS ACTION ALLEGATIONS

111. Plaintiff, on behalf of itself and the proposed Class, seeks monetary damages against GSK based on allegations of anticompetitive conduct in the market for Flonase and its AB-rated generic equivalents.

112. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a), (b)(2) and (b)(3), as representative of a Class defined as follows:

> All Third Party Payor entities which purchased, paid for, administered and/or reimbursed for fluticasone propionate nasal spray throughout the United States, whether branded Flonase or its generic equivalent, intended for consumption their members, employees, plan participants, beneficiaries or insureds from the date generic fluticasone propionate nasal spray could have entered the market (August 2004) until the full effects of generic competition had been realized.

Excluded from the Third Party Payor Class are: (1) Defendants and their officers, directors, management, employees, predecessors-in-interest, successors-in-interest, assignees or affiliates, subsidiaries; (2) The United States and/or State governments and their agencies and departments, except to the extent they purchased branded Flonase or its generic equivalents for their employees or others covered by a government employee health plan; and, (3) all persons or entities who purchased branded Flonase in or its AB-Rated generic equivalent for purposes of resale or directly from Defendants or their affiliates.

113. Members of the Third Party Payor Class are so numerous that joinder is impracticable. Plaintiff believes there are hundreds, if not thousands, of Class members spread across the United States whose identities can be obtained readily.

114. Plaintiff's claims are typical of the claims of the members of the Third Party Payor Class. Plaintiff's and all members of the Third Party Payor Class were damaged in the same way by the same wrongful conduct of GSK, *i.e.*, they paid some or all of the artificially inflated prices for fluticasone propionate and were deprived of the benefits of competition from cheaper generic versions of Flonase as a result of GSK's wrongful conduct.

115. There are no defenses of a unique nature that may be asserted against Plaintiff individually, as distinguished from the other members of the Third Party Payor Class, and the relief sought is common to the Third Party Payor Class. Plaintiff is a typical Third Party Payor of Flonase, and has no conflict with any other member of the Third Party Payor Class. Moreover, Plaintiff's interests are coincident with, and not antagonistic to, those of the Third Party Payor Class. As such, Plaintiff's will fairly and adequately protect and represent the interests of the Third Party Payor Class.

116. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation in the pharmaceutical industry.

117. Questions of law and fact common to the members of the Third Party Payor Class predominate over questions, if any, that may affect only individual Class members because GSK has acted on grounds generally applicable to the entire Class thereby making monetary and equitable relief with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in GSK's wrongful conduct.

118. Questions of law and fact common to the Third Party Payor Class include:

a) whether GSK delayed or prevented generic manufacturers from coming to market in the United States;

b) whether the petitioning to the FDA by GSK was objectively baseless;

c) whether GSK maintained or prolonged its monopoly power by illegally or improperly delaying generic entry through, *inter alia*, the filing of sham citizen petitions with the FDA;

d) whether direct proof of GSK's monopoly power is available, and if available, whether it is sufficient to prove GSK's monopoly power without the need to also define a relevant market;

e) to the extent a relevant market or markets must be defined, what that definition is;

f) whether the activities of GSK as alleged herein have substantially affected interstate commerce; and

g) whether, and to what extent, GSK's conduct caused antitrust injury to Plaintiff and the members of the Third Party Payor Class, and if so, the appropriate measure of damages.

119. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

120. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

X. CLAIMS FOR RELIEF

COUNT I
Monopolization Under State Law

121. Plaintiff re-alleges the preceding paragraphs as though set forth herein.

122. At all relevant times, Defendant has had monopoly power in the market for Flonase and/or fluticasone propionate products.

123. As described above, Defendant used various illegal, deceptive, willful and exclusionary means as part of an overall scheme to improperly maintain and extend patent protection for Flonase and/or fluticasone propionate by wrongfully manipulating the Hatch-Waxman statutory scheme, and to abuse and extend the monopoly power created thereby. Defendant accomplished this scheme by, among other things: (a) wrongfully filing a citizen petitions with the FDA in an attempt to delay generic versions of Flonase from entering the market; (b) wrongfully filing two supplements to its citizen petition with the FDA consistent with its efforts to delay generic versions of Flonase from entering the market; and (c) wrongfully petitioning the FDA for a Stay of Action in furtherance of its efforts to delay generic versions of Flonase from entering the market.

124. The goal, purpose and effect of GSK's scheme was to prevent, delay and/or minimize the successful entry of AB-rated generic fluticasone propionate, which would have sold in the United States at prices significantly below GSK's prices for Flonase, and would thereby have caused the average market price of fluticasone propionate to decline dramatically.

125. Moreover, the purpose and effect of Defendant's scheme was to exclude generic competition from the Flonase and/or fluticasone propionate market in order to maintain market power in the market for generic fluticasone propionate, charge supracompetitive prices, and reap unlawful monopoly profits.

126. Defendant's acts of monopolization were undertaken with specific intent to monopolize the market for Flonase and/or fluticasone propionate.

127. Plaintiff and members of the Third Party Payor Class paid for substantial amounts of Flonase and/or fluticasone propionate.

128. As a result of Defendant's illegal conduct, Plaintiff and members of the Third Party Payor Class were compelled to pay, and did pay, more than they would have paid for fluticasone propionate in the absence of Defendant's illegal conduct. But for Defendant's illegal conduct, competitors would have begun marketing generic versions of Flonase well before they actually did.

129. Had manufacturers of generic fluticasone propionate entered the market and lawfully competed with GSK in a timely fashion, Plaintiff and other members of the Third Party Payor Class would have substituted lower-priced generic fluticasone propionate for the higher-priced name-brand Flonase for some or all of their fluticasone propionate requirements, and/or would have paid lower net prices on their remaining Flonase purchases

130. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Ariz. Rev. Stat. Ann. § 44-1401, *et seq.*, with respect to purchases of Flonase and/or fluticasone propionate in Arizona by members of the Third Party Payor Class.

131. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Cal. Bus. & Prof. Code §§16720, *et seq.*, with respect to purchases of Flonase and/or fluticasone propionate in California by members of the Third Party Payor Class.

132. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of D.C. Code Ann. §§28-4501, *et seq.*, with respect to purchases of Flonase and/or fluticasone propionate in the District of Columbia by members of the Third Party Payor Class.

133. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of 740 Ill.Comp. Stat. Ann. §10/7(2), *et seq.*, with respect to purchases of Flonase and/or fluticasone propionate in Illinois by members of the Third Party Payor Class.

134. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in Iowa with respect to purchases of Flonase and/or fluticasone propionate in Iowa by members of the Third Party Payor Class.

135. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Kan. Stat. Ann. §§50-161, *et seq.,* with respect to purchases of Flonase and/or fluticasone propionate in Kansas by members of the Third Party Payor Class.

136. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Me. Rev. Stat. Ann. 10 §1101, *et seq.,* with respect to purchases of Flonase and/or fluticasone propionate in Maine by members of the Third Party Payor Class.

137. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Mich. Comp. Laws Ann. §§445.771, *et seq.,* with respect to purchases of Flonase and/or fluticasone propionate in Michigan by members of the Third Party Payor Class.

138. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Minn. Stat. §§325D.52, *et seq.,* with respect to purchases of Flonase and/or fluticasone propionate in Minnesota by members of the Third Party Payor Class.

139. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Neb. Code Ann. §§59-801, *et seq.*, with respect to purchases of Flonase and/or fluticasone propionate in Nebraska by members of the Third Party Payor Class.

140. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Nev. Rev. Stat. Ann. §§598A, *et seq.*, with respect to purchases of Flonase and/or fluticasone propionate in Nevada by members of the Third Party Payor Class.

141. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of N.H. Rev. Stat. § 356:11, *et seq.*, with respect to purchases of Flonase and/or fluticasone propionate in New Hampshire by members of the Third Party Payor Class.

142. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of N.M. Stat. Ann., §§57-1-3(A) & (C), *et seq.,* with respect to purchases of Flonase and/or fluticasone propionate in New Mexico by members of the Third Party Payor Class.

143. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of New York General Business Law §§340, *et seq.,* (the Donnelly Act) with respect to purchases of Flonase and/or fluticasone propionate in New York by members of the Third Party Payor Class.

144. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of N.C. Gen. Stat. §§75-16, *et seq.,* with respect to purchases of Flonase and/or fluticasone propionate in North Carolina by members of the Third Party Payor Class.

145. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of N.D. Cent. Code §§51-08.1-01, *et seq.*, with respect to purchases of Flonase and/or fluticasone propionate in North Dakota by members of the Third Party Payor Class.

146. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of S.D. Codified Laws Ann. §§37-1, *et seq.*, with respect to purchases of Flonase and/or fluticasone propionate in South Dakota by members of the Third Party Payor Class.

147. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Tenn. Code Ann. §§47-25-101, *et seq.*, with respect to purchases of Flonase and/or fluticasone propionate in Tennessee by members of the Third Party Payor Class.

148. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Utah Code Ann. §76-10-919, *et seq.*, with respect to purchases of Flonase and/or fluticasone propionate in California by members of the Third Party Payor Class.

149. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Vt. Stat. Ann. 9, §2465, *et seq.*, with respect to purchases of Flonase and/or fluticasone propionate in Vermont by members of the Third Party Payor Class.

150. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of W.Va. Code §§47-18-1, *et seq.*, with respect to purchases of Flonase and/or fluticasone propionate in West Virginia by members of the Third Party Payor Class.

151. Defendant has intentionally and wrongfully maintained its monopoly power in the relevant market in violation of Wis. Stat. Ann. §133.18, *et seq.*, with respect to purchases of Flonase and/or fluticasone propionate in West Virginia by members of the Third Party Payor Class.

152. Plaintiff and members of the Third Party Payor Class have been injured in their business or property by reason of Defendant's antitrust violations alleged in this Count. Their injury consists of paying higher prices for Flonase and/or fluticasone propionate prescription drugs than they would have paid in the absence of those violations.

153. The injury to Plaintiff and the Third Party Payor Class is the type of injury state antitrust laws were designed to prevent, and the injury flows from Defendant's unlawful conduct.

154. Plaintiff and the Third Party Payor Class seek damages and multiple damages as permitted by law for their injuries by Defendant's violations of the aforementioned statutes.

COUNT II
Unfair and Deceptive Trade Practices Under State Law

155. Plaintiff re-allege the preceding paragraphs as though set forth herein.

156. Defendant engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection statutes listed below by: (a) wrongfully filing a citizen petition with the FDA in an attempt to delay generic versions of Flonase from entering the market; (b) wrongfully filing two supplements to its citizen petition with the FDA consistent with its efforts to delay generic versions of Flonase from entering the market; and (c) wrongfully petitioning the FDA for a Stay of Action in furtherance of its efforts to delay generic versions of Flonase from entering the market. As a direct and proximate result of Defendant's anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiff and class members were deprived of the opportunity to purchase a generic version of Flonase and were forced to pay higher prices for fluticasone propionate from May 19, 2004 until the anticompetitive effects of Defendant's conduct ceased.

157. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Bus. & Prof. Code §17200, *et seq.*

158. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Colo. Rev. Stat. §6-2-101, *et seq.*

159. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Del.Code. Ann. Tit. 6 §§ 2501 - 2598.

160. Defendant has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code §28-3901, *et seq.*

161. Defendant has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Fla. Stat. Ann. §§501.201, *et seq.*

162. Defendant has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of 815 Ill. Comp. Stat. 505/1, *et seq.*

163. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. §205-A, *et seq.*

164. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*

165. Defendant has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Mich. Comp. Laws. Ann. §445.901, *et seq.*

166. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Missouri Stat. §407.010, *et seq.*

167. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. §59-1601, *et seq.*

168. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. §57-12-1, *et seq.*

169. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. §75-1.1, *et seq.*

170. Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. §2451, *et seq.*

171. Defendant has engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of W.Va. Code §46A-6-101, *et seq.*

172. Defendant has engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wis. Stat. Ann. §§425.101, *et seq.*

173. Plaintiff and members of the Third Party Payor Class have been injured by reason of Defendant's anticompetitive, unfair or deceptive acts alleged in this Count. Their injury consists of paying higher prices than they would have paid in the absence of these violations. This injury is of the

type the state consumer protection statutes were designed to prevent and directly results from Defendant's unlawful conduct.

COUNT III
Unjust Enrichment

174. Plaintiff re-alleges the preceding paragraphs as though set forth herein.

175. Defendant has benefited from the monopoly profits on its sales of Flonase resulting from the unlawful and inequitable acts alleged in this Complaint.

176. Defendant's financial benefits resulting from its unlawful and inequitable conduct are traceable to overpayments for Flonase by Plaintiff and members of the Third Party Payor Class.

177. Plaintiff and the Third Party Payor Class have unknowingly conferred upon Defendant an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and the Third Party Payor Class.

178. The economic benefit of overcharges and unlawful monopoly profits derived by Defendant through charging supra-competitive and artificially inflated prices for Flonase is a direct and proximate result of Defendant's unlawful practices.

179. The financial benefits derived by Defendant rightfully belong to Plaintiff and the Third Party Payor Class, as Plaintiff and the class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of Defendant.

180. It would be inequitable for the Defendant to be permitted to retain any of the overcharges for Flonase derived from Defendant's unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

181. Defendant should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Third Party Payor Class all unlawful or inequitable proceeds received by it.

182. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendant traceable to Plaintiff and the Third Party Payor Class.

183. Plaintiff and the Third Party Payor Class have no adequate remedy at law.

DEMAND FOR RELIEF

WHEREFORE, Plaintiff, on behalf of itself and the Third Party Payor Class, requests that:

A. The Court determine that this action may be maintained as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, and direct that reasonable notice of this action, as provided by Rule 23(c)(2) of the Federal Rules of Procedure, be given to the Class;

B. Certify Plaintiff as the representative of the Third Party Payor Class and designate its counsel as counsel for the Third Party Payor Class;

C. Adjudge and decree the acts alleged herein, pursuant to Fed. R. Civ. P. 57 and 18 U.S.C. §2201(a), to be in violation of the state laws identified above;

D. Award Plaintiff and the Third Party Payor Class actual damages and multiple damages or punitive damages where available by law in an amount to be determined at trial;

E. Award Plaintiff and the Third Party Payor Class equitable relief in the nature of disgorgement, restitution, and create a contructive trust to remedy Defendant's unjust enrichment;

F. Permanently enjoin the Defendant from continuing its unlawful conduct, so as to assure that similar anticompetitive conduct does not occur in the future;

G. Award Plaintiff and the Third Party Payor Class their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grant any such other further relief to which Plaintiff may be entitled and/or is necessary to correct the anticompetitive effects caused by the unlawful conduct of Defendant and as the Court deems just and/or equitable.

JURY TRIAL DEMANDED

Plaintiff demands trial by jury on all issues so triable.

Dated: July 24, 2012

Nicholas E. Chimicles
Joseph G. Sauder
Benjamin F. Johns
Christina Donato Saler
CHIMICLES & TIKELLIS LLP
One Haverford Centre
361 West Lancaster Avenue
Haverford, Pennsylvania 19041
T: (610) 642-8500

Mark M. Sandmann
GIBSON & SHARPS
9420 Bunsen Parkway, Suite 250
Louisville, KY 40220
Telephone: (502) 214-8605
Email: mms@gibsonsharps.com

Marvin A. Miller
Lori A. Fanning
MILLER LAW LLC
115 S. LaSalle Street, Suite 2910
Chicago, IL 60603
Telephone: (312) 332-3400
Email: MMiller@millerlawllc.com
LFanning@millerlawllc.com

Pamela B. Slate
HILL, HILL, CARTER, FRANCO, COLE & BLACK, P.C.
425 South Perry Street
Montgomery, Alabama 36104
Telephone: (334) 386-4380
Email: pslate@hillhillcarter.com

Counsel for Plaintiff Medical Mutual of Ohio